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EXAMINER	
ODELL, LINDSAY T	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,338	ANDERS ET AL.	
	Examiner	Art Unit	
	Lindsay Odell	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29,37,45 and 47-51* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45 and 47-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/018806.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *22 July 2004*. 19 August 2004
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. The instant Application is a continuation of U.S. Application U.S. 09/018,806, filed February 4, 1998, now abandoned. In response to the previous Office action, a first action on the merits (mailed on February 14, 2004), Applicants filed a response received on July 22, 2004, which was non-compliant because a complete listing of all the claims was not present and each claim was not provided with the proper status identifier. Applicant's filed an amendment to the claims on May 5, 2005 correcting this error. Claims 30-36, 38-44 and 46 have been cancelled, and new claims 50-51 have been added. Thus, Claims 1-29, 37, 45, and 47-51 are pending in the instant Office action.

Election

2. Applicant's election of Group XVI, Claims 30-36 and 45-49, in a paper received on December 11, 2003 is acknowledged. Affirmation of this election was not made by Applicant in the response filed July 22, 2004 to the Office action mailed on February 17, 2004. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

Claims 1-29, 37, 45, and 47-51 are pending in the instant Office action. Claims 1-29 and 37 are withdrawn from consideration as non-elected inventions. Claims 45 and 47-51 will be examined herein.

3. The Examiner notes that if product claims in Group XVI, claims 45 and 47-51, are found to be allowable, process claims in Groups VIII-XIV, claims 15-20 and 37, are subject to rejoinder with claims 45 and 47-51.

4. This application contains claims drawn to an invention nonelected with traverse in the paper filed December 11, 2003. There is no possible rejoinder of non-elected claims 1-14 and 21-29 with the elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

5. As previously noted, the instant application is granted the benefit of priority for the foreign application 9702218.0 filed on February 4, 1997 filed in the United Kingdom and U.S. application 09/018,806 filed on February 4, 1998.

Information Disclosure Statement

6. The information disclosure statement (IDS) filed on July 22, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The following references were not considered for the reasons described below:

a) Copies of the documents ES 550549, A.L. Demain, and Sambrook *et al.* are not found.

All other documents in said Information Disclosure Statement were considered as noted by the examiner's initials in the attached copy. Examiner notes that the reference King *et al.*, which

was not previously considered because copies of the references were not found has been fully considered. The Examiner further notes that the reference Paradkar *et al.* (1995) has been considered, but is listed twice on the IDS; thus, the second listing of Paradkar *et al.* is not initialed.

7. The information disclosure statements filed on August 19, 2004 has been reviewed, and their references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

Compliance with the Sequence Rules

8. A new statement that the CRF and the paper copies of the sequence listing are the same was received on July 22, 2004. The instant application is in compliance with the sequence rules by virtue of the aforementioned statement *and* Applicant's amendment to the Brief Description of the Drawings for Figure 1, which provides SEQ ID identification for the polypeptide sequences in Figure 1.

Withdrawn Objections to the Specification

9. The previous objection to the specification for lacking updated continuity data in the first paragraph is withdrawn by virtue of Applicant's amendment.

10. The previous objection to the specification for containing pages 13-29 that contain figures that is withdrawn by virtue of Applicant's deletion of pages 13-29 of specification.

11. The previous objection to the specification is withdrawn by virtue of Applicant's amendment.

The previous objection to the specification for being confusing with respect to the sequence listing is withdrawn by virtue of Applicant's amendment.

Maintained Objections to the Specification

12. The objection to the specification is because the title is not descriptive is maintained and amended. Applicant's amendment to the title has been fully considered; however the amended title, "*Streptomyces* Culture Media Comprising Clavulanic Acid and Pharmaceutical Compositions", is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: *Streptomyces* culture media. While the specification discloses Soya-Flour media (see page 8), support is not found in the specification for the genus of *Streptomyces* culture media. In addition, the generic term "Pharmaceutical Compositions" is not descriptive of the instant claims.

As stated in the previous Office action, a new title is required that is clearly indicative of the invention to which the elected claims are drawn (see M.P.E.P. § 606.01). The Examiner suggests the following new titles:

---Isolated Clavulanic Acid, Obtainable from Fermentation of Modified *Streptomyces*---

or

---Isolated Clavulanic Acid that is Free of 5S clavams.

Applicant is required to cancel the new matter in the reply to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant term.

Appropriate correction of all of the above points is required.

13. The objection to the specification because the Abstract does not completely describe the disclosed subject matter is maintained and amended. Applicant has amended the Abstract as follows "Novel *Streptomyces* culture media for improving the manufacture of 5R clavams, eg. clavulanic acid. and pharmaceutical compositions obtainable from *S. clavuligerus*". The amended Abstract does not overcome the previous objection because it is not a complete and concise statement of the technical disclosure. The disclosure teaches that the manufacture of 5R clavams can be improve by fermentation of *Streptomyces clavuligerus* in which particular genes specific for 5S clavam biosynthesis are defective; however, a description of culture media that improves 5R clavam manufacture, as stated in the amended Abstract, is not found. In addition, the phrase "pharmaceutical compositions obtainable from *S. clavuligerus*" is not a concise description of the compositions disclosed, which are compositions of 5R clavams *free of the 5S clavams* clavam-2-carboxylate, 2-hydroxymethylclavam and 2-(3-alanyl)clavam obtained by fermenting the aforementioned *S. clavuligerus* in which particular genes are defective. Lastly, the Abstract of the specification, as amended, is objected for the following typographical errors: there is a period missing from the phrase "eg." after the "e", and there is a period after the word "clavulanic acid.", which should be changed to a comma.

As previously stated, the Examiner suggests inclusion of the description of the purified form of clavulanic acid produced by the disclosed methods (i.e., ---5R clavams, e.g. clavulanic acid, free of 5S clavams such as clavam-2-carboxylate, 2-hydroxymethylclavam and 2-(3-

alanyl)clavam). The Examiner further suggests inclusion of a description of the disclosed method by which manufacture of 5R clavams is improved (i.e. ---by fermentation of *Streptomyces clavuligerus* in which particular genes involved in 5S clavam biosynthesis are defective). Appropriate correction on all of the above points is required.

Withdrawn Claim Objections

14. The previous objection to claims 30-32 and 35-36 for depending from non-elected is withdrawn by virtue of Applicant's cancellation of the claims.

15. The previous objection to claim 45 is objected to for a typographical error is withdrawn by virtue of Applicant's amendment. Correction is required.

Withdrawn Claim Rejections - 35 U.S.C. § 112

16. The previous rejection of claims 30-32 and 35-36 under 35 U.S.C. § 112, second paragraph, as being indefinite because they are unclear is withdrawn by virtue of Applicant's cancellation of the claims.

17. The previous rejection of claims 45 and 47-49 under 35 U.S.C. § 112, second paragraph, as being indefinite because the SEQ ID NO's recited in claim 45 are found only in *S. clavuligerus,* not any *Streptomyces,* is withdrawn by virtue of Applicant's amendment.

18. The previous rejection of claims 31, 33, and 34 under 35 U.S.C. § 112, second paragraph, as being indefinite is withdrawn by virtue of Applicant's cancellation of the claims.

19. The previous rejection of claims 45-49 under 35 U.S.C. § 112, second paragraph, as being indefinite because selected DNAs must be disrupted or made defective in any *Streptomyces,* including DNAs specifically found only in *S. clavuligerus,* is withdrawn by virtue of Applicant's amendment to claims 45 and 47-49 and cancellation of claim 46.

20. The previous rejection of claims 45-49 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement because no support is found for disrupting orfup2 or orfup3 in S. clavuligerus to produce clavulanic acid and because the concept of degenerate variants is not presented in the specification as originally filed is withdrawn by virtue of Applicant's amendments.

21. The previous rejection of claims 30-32 and 35-36 35 U.S.C. § 112, first paragraph, written description, because the claims are drawn to DNA that is claimed solely by function (albeit unclear function) and without any structural limitations is withdrawn by virtue of Applicant's cancellation of the claims.

Withdrawn Claim Rejections - 35 U.S.C. § 101

22. The previous rejection of claim 30 under 35 U.S.C. § 101, utility, because the claimed invention is directed to non-statutory subject matter is withdrawn by virtue of Applicant's cancellation of the claim.

Withdrawn Claim Rejections - 35 U.S.C. § 102

23. The previous rejection of claims 30-36 and 46 under 35 U.S.C. § 102(b) as being anticipated by Fleming *et al.* (USPN 4,367,175) is withdrawn by virtue of Applicant's cancellation of the claims.

24. The previous rejection of claims 30-34 and 46 under 35 U.S.C. § 102(b) as being anticipated by Woroniecki *et al.* (USPN 5,130,241) is withdrawn by virtue of Applicant's cancellation of the claims.

Maintained Claim Rejections - 35 U.S.C. § 102

25. The rejection of claims 45 and 47-49 under 35 U.S.C. § 102(b) as being anticipated by Fleming *et al.* (USPN 4,367,175) is maintained and amended. With respect to the instant claims, Applicants argue that Fleming *et al.* do not disclose a pharmaceutical composition comprising clavulanic acid and free of 5S clavams. Applicant's arguments have been fully considered, but are not found persuasive for the following reasons. The purity of the clavulanic acid isolated by Fleming *et al.* is demonstrated by optical rotation, UV spectrum, IR spectrum, NMR spectrum, TLC, and paper ionophoresis (see columns 14-15) as well as elemental analysis for the

potassium salt (see column 18). As previously stated, particularly the IR, NMR, and elemental analysis showed no signs of impurities. The clavulanic acid isolated by Fleming *et al.* is free of 5S clavams because it is demonstrated by Fleming *et al.* to be pure using methods that would detect if 5S clavam if it was present. Furthermore, although the clavulanic acid taught by Fleming *et al.* is taught to be used in a pharmaceutical composition (see Abstract) the term "pharmaceutical composition" in the claims does not carry any patentable weight because it merely indicates the intended use of the composition comprising clavulanic acid free of 5S clavams. The term "pharmaceutical composition" in the claims does not impose a real limitation on the physical or chemical properties of the instant composition. Thus, Fleming *et al.* anticipate claims 45 and 47-49 because they teach a composition of clavulanic acid free of 5S clavams.

26. The previous rejection of claims 45 and 47 under 35 U.S.C. § 102(b) as being anticipated by Woroniecki *et al.* (USPN 5,130,241) is maintained and amended. With respect to the instant claims, Applicants argue that Woroniecki *et al.* do not disclose a pharmaceutical composition comprising clavulanic acid and free of 5S clavams. Applicant's arguments have been fully considered, but are not found persuasive for the following reasons. As stated in the previous Office action, the clavulanic acid isolated by Woroniecki *et al.* is made by specific enzymatic conversion of Z-(2S,5S)-3-(β-aminoethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylic acid (compound I) to clavulanic acid (see column 35, example 34). The enzyme used in the reaction is purified such that 5S clavams would not be present, as previously stated. In addition, the enzyme specifically converts compound I to clavulanic acid, and does not produce other clavams (i.e. 5S clavams), as shown by ^{1}H-NMR analysis, chromatography and mass spectrometry of the [^{13}C] labeled product of the enzymatic conversion of [^{13}C]-labeled

compound I (see columns 34-35, example 33). Therefore, no 5S clavams are present in the clavulanic acid taught by Woroniecki *et al.* Furthermore, the term "pharmaceutical composition" in the claims carries no patentable weight, as previously described. Thus, Woroniecki *et al.* anticipate claims 45 and 47.

Withdrawn Claim Rejections - 35 U.S.C. § 103

27. The previous rejection of claims 35 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Woroniecki *et al.* (USPN 5,130,241) in view of Fleming *et al.* (USPN 4,367,175) is withdrawn by virtue of Applicant's cancellation of the claims.

Maintained Claim Rejections - 35 U.S.C. § 103

28. The previous rejection of claims 48 and 49 under 35 U.S.C. § 103(a) as being unpatentable over Woroniecki *et al.* (USPN 5,130,241) in view of Fleming *et al.* (USPN 4,367,175) is maintained and amended. Applicants argue that Woroniecki *et al.* do not teach the combination of clavulanic acid with beta-lactam antibiotics. In addition, Applicant's argue that Fleming *et al.* and Woroniecki *et al.* teach only removing impurities in general from clavulanic acid, and that neither specifically indicate clavulanic acid free from 5S clavams. Applicant's arguments have been fully considered, but are not found persuasive for the following reasons.

As noted above, Woroniecki *et al.* teach clavulanic acid that is free of 5S clavams. In addition, as noted in the previous office action, Fleming *et al.* teach purified clavulanic acid in combination with amoxycillin, a beta-lactam antibiotic.

The Examiner reminds Applicant that under 35 U.S.C. § 103:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter ***as a whole*** would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. (emphasis added).

Thus, under 35 U.S.C. § 103(a), an invention may be anticipated by combination of teachings "as a whole" in the prior. A combination of references, as opposed to a single reference, is sufficient to teach every aspect of the instant claims. Therefore, it is not necessary under 35 U.S.C. § 103 that Woroniecki *et al.* teach the combination of clavulanic acid with beta-lactam antibiotics or that Fleming *et al* teach clavulanic acid that is free of 5S clavams. (Although, the Examiner notes that Fleming *et al.* do teach clavulanic acid that is free of 5S clavams, as described above).

As stated in the previous Office action, it would have been obvious at the time of the invention to one of ordinary skill in the art to combine the teachings of Woroniecki *et al.* and Fleming *et al.* to make pure clavulanic acid (free of 5S clavams) in combination with amoxycillin, a beta-lactam antibiotic, because of the well-known protective effective of clavulanic acid against β-lactamase degradation of β-lactam antibiotics (see both Woroniecki *et al.* and Fleming *et al.*). One would have been motivated to combine the above teachings and make the invention due to the well-known pharmaceutical effectiveness of β-lactam antibiotics in the absence of degradation (see Fleming *et al.*).

NEW *Claim Rejections - 35 U.S.C. § 112*

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

29. Claims 50-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase *"Streptomyces* culture media" is unclear as to the metes and bounds it imparts on the claimed subject matter. It is unclear if *Streptomyces* culture media is culture media containing *Streptomyces,* culture media for growing *Streptomyces* bacteria, or culture media in which *Streptomyces* has been grown and removed from (i.e. by centrifugation and decantation). A definition for the term "*Streptomyces* culture media" is not found in the specification, nor is it defined with a single meaning in the art. The composition of *Streptomyces* culture media is unclear. By "*Streptomyces* culture media, do Applicant's mean the Soya-Flour medium they used to grow *S. clavuligerus* on page 8 of the specification? If so, the Examiner notes that this limitation cannot be read into the claim as written. Clarification of the term is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

30. Claims 50-51 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. Support is not found in the specification for the genus of "***Streptomyces* culture media** containing clavulanic acid and free of 5S clavam as measured by HPLC analysis." (emphasis added). The specification discloses Soya-Flour media containing clavulanic acid and free of 5S clavam as measured by HPLC analysis (see pages 8 and 10). However, Soya-Flour media does not describe the genus of *Streptomyces* culture media. In addition, support for the claims is not found on page 3, lines 14-20 of the specification, as suggested by Applicant in the response filed July 22, 2004; thus, *Streptomyces* culture media, as it appears in claims 50 and 51, constitutes new matter.

The Examiner notes that obviousness is not the standard for the addition of new limitations to the disclosure as filed. It is noted that entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

Summary of Pending Issues

31. The following are a summary of the issues pending in the instant application:

a) The specification stands objected to because the Title and Abstract are not descriptive and the Title contains new matter.
b) Claims 45 and 46-49 stand rejected under 35 U.S.C., § 102 (b), as being anticipated by Fleming *et al.*
c) Claims 45 and 46-47 stand rejected under 35 U.S.C., § 102 (b), as being anticipated by Woroniecki *et al.*
d) Claims 48-49 stand rejected under 35 U.S.C., § 103 (a), as being unpatentable over Woroniecki *et al.*, in view of Fleming *et al.*
e) New claims 50-51 are rejected under 35 U.S.C. § 112, second paragraph, indefiniteness, for the phrase "*Streptomyces* culture media".

f) New claims 50-51 are rejected under 35 U.S.C. § 112, first paragraph, written description, for the phrase "*Streptomyces* culture media".

Conclusion

32. Claims 45 and 47-51 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy ms set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1. 136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.
July 18, 2005

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER